

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29, 30, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacMillan (US 3,159,175) in view of Bartholomew et al. (US 5,176,662), Ohringer (US 3,811,466), and Haarala et al. (US 2002/0156430 A1).

With regard to claim 29, MacMillan teaches a pressure activated valve for medical applications, comprising: a housing (Fig. 2 19 and 31); and a resilient flow control membrane disposed within the housing (Fig. 3 members 42, 43, and 44), said flow control membrane comprising: a resilient first membrane portion (Fig. 3 portion 44) and an annular base member stacked upon said first membrane portion (Fig. 3 members 42 and 43). MacMillan teaches members 42 and 43 to be a gasket (Col. 2 line 5) but does not explicitly teach the material of members 42 and 43. However, Bartholomew et al. teach o-ring gaskets which are made of elastomeric rubber material (Col. 4 lines 11-19). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an elastomeric material for the gaskets in MacMillan because Bartholomew et al. teach this is an art effective material for sealing. MacMillan does not teach a plurality of curved slits. However, Ohringer teaches using a plurality of slits can be used to allow for greater flow (Col. 4 lines 31-35). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a

plurality of slits in the device of MacMillan as Ohringer teaches this is beneficial as a means for controlling flow. Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Additionally, Haarala et al. teach a pressure activated slit valve which can equivalently be straight or curved (Figs. 5B and 8B). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use curved slits instead of straight in the device of MacMillan as in Ohringer because Ohringer teaches these to be art recognized effective equivalents.

With regard to claim 30, Fig. 3 seating portion in 31 (Col. 2 lines 5-10).

With regard to claim 37, MacMillan does not specifically disclose the membrane portions are formed as a single piece. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to integrally form the first membrane portion and annular base portion since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. (*Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)).

3. Claim 31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacMillan (US 3,159,175), Bartholomew et al. (US 5,176,662), Ohringer (US 3,811,466), and Haarala et al. (US 2002/0156430 A1) as applied to claim 29 above, and further in view of Moorehead (US 5,984,902).

With regard to claim 31, MacMillan does not explicitly disclose the first membrane and base member are adhesively bonded. However, Moorehead does teach that the annular member

around the valve can be retained effectively using adhesion among a variety of bonding means (Col. 10 lines 11-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to bond the first membrane and annular base member with adhesive in MacMillan because Moorehead teaches that adhesive is suitable for use for retention and it is an art recognized effective way of securing two things together so as to maintain them in a desired position.

With regard to claims 35 and 36, MacMillan teaches a device substantially as claimed. MacMillan does not disclose both portions are made of silicone. However, Moorehead teaches a slit valve made of silicone rubber which is beneficial because it has good flexing and memory characteristics (Col. 8 lines 23-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use silicone for both portions because Bartholomew et al. teach using a rubber material for the annular base and Moorehead teaches silicone is a beneficial rubber because it has good flexing and memory characteristics.

4. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacMillan (US 3,159,175), Bartholomew et al. (US 5,176,662), Ohringer (US 3,811,466), and Haarala et al. (US 2002/0156430 A1) as applied to claim 29 above, and further in view of Fischer et al. (US 5,944,698).

With regard to claims 32 and 33, MacMillan teaches a pressure activated valve substantially as claimed. MacMillan does not disclose specific thickness range for the membrane. However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col.

6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use a first membrane with a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 in the device of MacMillan as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.

With regard to claim 34, MacMillan teaches a pressure activated valve substantially as claimed. MacMillan does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the first membrane and base member (Figs. 3 and 7 elements 128, 124) in MacMillan as applied to claims 32 and 33. It directly follows that the thickness of the seating portion will be between 1 and 20 times the thickness of the lumen occluding portion. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.

5. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacMillan (US 3,159,175) in view of Bartholomew et al. (US 5,176,662).

With regard to claim 38, MacMillan teaches a pressure activated valve for medical applications, comprising: a housing defining a lumen therethrough (Fig. 2 members 19 and 31);

and a flow control membrane disposed across the lumen (Fig. 3 members 42, 43, 44), the flow control membrane comprising: a resilient first membrane portion (Fig. 3 member 44); and an annular base member stacked upon said first membrane portion such that the thickness of the flow control membrane is increased at a periphery thereof (Fig. 3 members 42 and 43), wherein the housing includes a membrane retention portion adapted to apply compression force to the periphery of the flow control membrane (Fig. 3 seating portion in 31 Col. 2 lines 5-10), and wherein the first membrane portion includes one or more slits therethrough, the one or more slits opening when subjected to a pressure of at least a predetermined threshold level (Fig. 3 slit 45, Col. 2 lines 19-21 and 55-60). MacMillan teaches members 42 and 43 to be a gasket (Col. 2 line 5) but does not explicitly teach the material of members 42 and 43. However, Bartholomew et al. teach o-ring gaskets which are made of elastomeric rubber material (Col. 4 lines 11-19). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an elastomeric material for the gaskets in MacMillan because Bartholomew et al. teach this is an art effective material for sealing.

6. Claims 29-31 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (US 5,984,902) in view of MacMillan (US 3,159,175), Bartholomew et al. (US 5,176,662), Ohringer (US 3,811,466) and Haarala et al. (US 2002/0156430 A1).

With regard to claim 29, Moorehead teaches a pressure activated valve for medical applications, comprising: a housing (Figs. 3 and 7 housing 112); and a resilient flow control membrane disposed within the housing, said flow control membrane comprising: a resilient first membrane (Figs. 3 and 7 element 128) and an annular base member stacked upon said first

membrane (Figs. 3 and 7 element 124), said first membrane comprising a slit extending therethrough, wherein said slit opens when subjected to a pressure of at least a predetermined threshold level (Figs. 11-13, Col. 11 lines 12-41). Moorehead do not specifically disclose a resilient annular base member. However, MacMillan teaches using gaskets on either side of a silt valve (Fig. 3, Col. 2 lines 5-10) and Bartholomew et al. teach o-ring gaskets which are made of elastomeric rubber material (Col. 4 lines 11-19). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an elastomeric material for an annular base member in Moorehead as in MacMillan and Bartholomew et al. MacMillan because Bartholomew et al. teach this is an art effective material for sealing and would help to prevent leakage. Moorehead does not teach a plurality of curved slits. However, Ohringer teaches using a plurality of slits can be used to allow for greater flow (Col. 4 lines 31-35). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a plurality of slits in the device of Moorehead as Ohringer teaches this is beneficial as a means for controlling flow. Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Additionally, Haarala et al. teach a pressure activated slit valve which can equivalently be straight or curved (Figs. 5B and 8B). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use curved slits instead of straight in the device of Moorehead as in Ohringer because Ohringer teaches these to be art recognized effective equivalents.

With regards to claim 30, Moorehead teaches a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 3 generally indicated at 116, Col. 10 lines 2-4).

With regard to claim 31, Moorehead does not explicitly disclose the first membrane and base member are adhesively bonded. However, Moorehead does teach that member 124 can be retained effectively using adhesion (Col. 10 lines 11-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to bond the first membrane and annular base member with adhesive because Moorehead teaches that adhesive is suitable for use for retention and it is an art recognized effective way of securing two things together so as to maintain them in a desired position.

With regard to claims 35 and 36, Moorehead teaches a slit valve made of silicone rubber which is beneficial because it has good flexing and memory characteristics (Col. 8 lines 23-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use silicone for both portions because Bartholomew et al. teach using a rubber material for the annular base and Moorehead teaches silicone is a beneficial rubber because it has good flexing and memory characteristics.

With regard to claim 37, Moorehead does not specifically disclose the membrane portions are formed as a single piece. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to integrally form the first membrane portion and annular base portion since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. (*Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)).

7. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (US 5,984,902), MacMillan (US 3,159,175), Bartholomew et al. (US 5,176,662), Ohringer (US 3,811,466), and Haarala et al. (US 2002/0156430 A1) as applied to claim 29 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

With regard to claims 32 and 33, Moorehead teaches a pressure activated valve substantially as claimed. Moorehead differs from claims 32 and 33 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col. 7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use a first membrane with a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 in the device of Moorehead as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.

With regard to claim 34, Moorehead teaches a pressure activated valve substantially as claimed. Moorehead differs from claim 34 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It



would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the first membrane and base member (Figs. 3 and 7 elements 128, 124) in Moorehead as applied to claims 32 and 33. It directly follows that the thickness of the seating portion will be between 1 and 20 times the thickness of the lumen occluding portion.

8. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (US 5,984,902) in view of MacMillan (US 3,159,175) and Bartholomew et al. (US 5,176,662).

With regard to claim 38, Moorehead teaches a pressure activated valve for medical applications, comprising: a housing defining a lumen therethrough (Figs. 3 and 7 housing 112); and a flow control membrane disposed across the lumen, said flow control membrane comprising: a resilient first membrane portion (Figs. 3 and 7 element 128) and an annular base member stacked upon said first membrane portion such that the thickness of the flow control membrane is increased at a periphery thereof (Figs. 3 and 7 element 124), wherein the housing includes a membrane retention portion adapted to apply compression force to the periphery of the flow control membrane (Fig. 3 generally indicated at 116, Col. 10 lines 2-4), and wherein the first membrane portion includes one or more slits extending therethrough, the one or more slits opening when subjected to a pressure of at least a predetermined threshold level (Figs. 11-13, Col. 11 lines 12-41). Moorehead do not specifically disclose a resilient annular base member. However, MacMillan teaches using gaskets on either side of a silt valve (Fig. 3, Col. 2 lines 5-10) and Bartholomew et al. teach o-ring gaskets which are made of elastomeric rubber material (Col. 4 lines 11-19). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an elastomeric material for an annular base member in

Moorehead as in MacMillan and Bartholomew et al. MacMillan because Bartholomew et al. teach this is an art effective material for sealing and would help to prevent leakage.

***Response to Amendment***

9. The amendments to the claims have been entered.

***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Regarding Applicant's arguments with respect to Moorehead, the Examiner does not find Moorehead to teach away from using a resilient membrane, the Examiner finds that a resilient annular member as used in Moorhead would still able to provide compression to the slit membrane portion, further one side of housing applies direct force to the annular base portion and the other side of the housing applies direct for to the slit membrane portion. Further, regarding Haarala the Examiner finds that regardless of the location of the slits they still function to open and close in response to pressure and are therefore analogous art and in the same filed of endeavor.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY SCHMIDT whose telephone number is (571)270-3648. The examiner can normally be reached on Monday through Thursday 7:00 AM to 4:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/  
Examiner, Art Unit 3767

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3763